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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOSEPH A. GONZALES, BOUN PRAVONG, RICHARD C. EWERS, and RICHARD L. MYERS

Appeal 2010-006566 Application 10/695,295 Technology Center 3700

Before LINDA E. HORNER, CHARLES N. GREENHUT, and MICHAEL L. HOELTER, *Administrative Patent Judges*.

HORNER, Administrative Patent Judge.

DECISION ON APPEAL

STATEMENT OF THE CASE

Joseph A. Gonzales et al. (Appellants) seek our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 1, 2, and 4-10 under 35 U.S.C. § 103(a) as unpatentable over Abramson (US 4,143,853; iss. Mar. 13, 1979), in view of either Weinstein (US 5,460,616; iss. Oct. 24, 1995) or Brustad (US 2003/0139756 A1; pub. Jul. 24, 2003), and Johnson (US 4,946,133; iss. Aug. 7, 1990). Claims 3 and 16-25 have been canceled, and claims 11-15 have been withdrawn. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

THE INVENTION

Appellants' claimed invention "relates generally to medical and surgical devices and more specifically to access seals adapted for use in urological procedures." Spec. 1, 1l. 9-10. Claims 1 and 6, reproduced below, are representative of the subject matter on appeal.

- 1. A surgical valve having an axis extending between a proximal end and a distal end, comprising:
- a housing including a proximal housing portion and a distal housing portion adjustably cooperating with the proximal housing portion to define a gel cavity;
- a seal material disposed in the gel cavity, the seal material including a gel having noncompressible characteristics, the gel having characteristics for creating a pressure on an instrument extending through the valve to form a seal around the instrument:

¹ The citation herein to the Specification is to the clean copy of the Replacement Specification dated October 8, 2008.

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> a proximal guide tube extending axially proximally from the proximal housing portion;

> the proximal guide tube facilitating insertion of a surgical instrument into the seal material; and

a distal guide tube extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal, wherein the proximal guide tube includes exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion, wherein

the proximal housing portion is adjustably movable axially relative to the distal housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve.

6. A surgical valve, comprising:

a first housing portion defining a gel cavity;

a seal material including a gel and having a node and an axial channel;

a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state; and

a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state.

ISSUES

The issues presented by this appeal are:

Did the Examiner articulate an adequate reason based on rational underpinnings to explain why one of ordinary skill in the art would have

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been led by the teaching of Johnson to modify the device of Abramson to make the proximal housing portion adjustably movable axially relative to the distal housing portion to create a locking force tending to inhibit movement of the instrument relative to the valve as called for in claims 1 and 10?

Did the Examiner show where the prior art discloses "a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state" as called for in claim 6?

ANALYSIS

Claims 1 and 10

The Examiner determined that ridge and groove 31, 32 of Abramson "are the means adjustably moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible seal on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve." Ans. 3. *See also* Ans. 6 ("Abramson clearly discloses a ridge 31 and groove 32 to create a locking force tending to inhibit movement of the instrument, see Figs. 1, 3-5 and col. 3, lines 32-54.") The Examiner also stated, however, that in Abramson "the proximal housing portion is not adjustably axially relative to the distal housing portion." Ans. 3. *See also* Ans. 6 ("The proximal housing portion 12 or 30 and distal portion 11 are pressed together with snapping in place of the detent while the claimed invention required adjustably movable axially.") The Examiner relied on Johnson to disclose a surgical valve having "[a] proximal housing portion [that] is adjustably movable axially relative to the distal housing portion to increase the pressure of the

seal/valve 10 on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve." Ans. 3. *See also* Ans. 6-7 (finding that the thread section of the proximal housing portion 27 is engaged with the thread section of distal housing portion 22 by being adjustably movable in the axial direction.) The Examiner determined that it would have been obvious "to modify the device of Abramson with the proximal housing [that] is adjustably movable axially relative to the distal housing, as taught by Johnson, in order to create a locking force for preventing movement of the instrument relative to the valve." Ans. 4. *See also* Ans. 7 ("[T]he device Abramson modified with the thread sections, as taught by Johnson, is provided in order to create a locking force for preventing movement of the instrument relative to the valve.")

Abramson discloses that during assembly of the male member 11 and female member 12, axially engaging detent surfaces 31 and 32 snap into register so that the members 11 and 12 exert an axial pinching force on the periphery of the valve disc 22 that places the domed portion 21 of the disc 20 under compression to keep the slit 22 normally sealed against the flow of fluid in either direction. Abramson, col. 2, ll. 63-67 and col. 3, ll. 1-5 and 10-18. Abramson does not disclose, however, that the compressive force on valve seal 20 is increased sufficiently during assembly to create a locking force tending to inhibit movement of an instrument relative to the valve. In fact, Abramson teaches using stops on the members 11 and 12 to prevent overstressing of the valve disc 20. Abramson, col. 3, ll. 32-39. Abramson states that "the valve, once assembled, cannot be disassembled, misadjusted,

or tampered with in any way" (col. 3, 1l. 48-50) and thus does not disclose that the male and female members, once assembled, are movably axially relative to one another to create the claimed locking force. Likewise, Johnson does not disclose a valve assembly capable of creating a locking force on an instrument passing through the valve. Johnson, col. 3, 1l. 47-53 (stating that a guide wire can be passed through the catheter introducer.)

We agree with Appellants' observation that "[t]he Examiner does not even attempt to explain why one skilled in the art would want to inhibit movement of an instrument relative to a valve." Reply Br. 7. As such, we are led to conclude that the Examiner's reason for the proposed modification to Abramson's valve is based on impermissible hindsight reconstruction. *Id.* Neither Weinstein nor Brustad cures this deficiency in the combination of Abramson and Johnson. Ans. 8 (stating that the locking force limitation is "covered in the device of Johnson.") As such, we do not sustain the rejection of independent claims 1 and 10 or dependent claims 2, 4, and 5 as unpatentable over Abramson in view of Weinstein or Brustad, and Johnson. *Claim 6*

Independent claim 6 calls for a surgical valve comprising a subassembly including a seal material, which includes a gel and having a node and an axial channel, disposed in the gel cavity of a first housing portion, the seal material "being configured with the channel in an open state." Appellants argue that "[t]he Examiner does not identify any disclosure or suggestion of an axial channel in an open state in any of the cited references." App. Br. 12. The Examiner responded that "[u]nder the

compression [t]he valve 20 also includes the channel at slit 22 to permit flow of fluid through the through-opening with resilient reclosure of the slit, col. 6, lines 14-20 and Figs. 1 and 3." Ans. 10.

The slit 22 of Abramson's rubber valve disc 20 appears to be in a closed state when the valve disc 20 is disposed in member 12 and prior to assembly with the member 11. Abramson, col. 3, Il. 26-31; fig. 5 (disclosing that the valve element 20 is preferably made with a diameter in the unstressed state that coincides with the inner diameter of member 12.) Thus, Abramson does not disclose "a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state" as called for in claim 6. As such, the Examiner has failed to show where the prior art discloses the claimed subassembly. Accordingly, we cannot sustain the rejection of claim 6 or dependent claims 7-9 as unpatentable over Abramson, in view of Weinstein or Brustad, and Johnson.

CONCLUSIONS

The Examiner did not articulate an adequate reason based on rational underpinnings to explain why one of ordinary skill in the art would have been led by the teaching of Johnson to modify the device of Abramson to make the proximal housing portion adjustably movable axially relative to the distal housing portion to create a locking force tending to inhibit movement of the instrument relative to the valve as called for in claims 1 and 10.

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The Examiner did not show where the prior art discloses "a subassembly including the seal material disposed in the gel cavity, the seal material being configured with the channel in an open state" as called for in claim 6.

DECISION

The decision of the Examiner to reject claims 1, 2, and 4-10 is REVERSED.

REVERSED

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